

Appl. No. 10/072,177
Amendment dated March 25, 2004
Reply to Office action of December 4, 2003

Amendments to the Claims:

This listing of claims replaces the prior version as presented in the application:

Claim 1 (original): A cytostatic anti-proliferative surgical wrap sheet of material adapted for being wrapped generally around tissues of a human body at the site of a surgical procedure, the sheet of material having a cytostatic anti-proliferative drug attached, the action of the cytostatic anti-proliferative drug being a reduction in the generation of scar tissue, the cytostatic anti-proliferative drug being selected from the group that includes sirolimus, anti-sense to c-myc (Resten-NG), tacrolimus (FK506), Everolimus and the any functional analog of sirolimus including: SDZ-RAD, CCI-779, 7-epi-rapamycin, 7-thiomethyl-rapamycin, 7-epi-trimethoxyphenyl-rapamycin, 7-epi-thiomethyl-rapamycin, 7-demethoxy- rapamycin, 32-demethoxy, 2-desmethyl and proline.

Claim 2 (original): The cytostatic anti-proliferative surgical wrap of claim 1 wherein the sheet of material is drug eluting and biodegradable.

Claim 3 (original): The cytostatic anti-proliferative surgical wrap of claim 1 wherein the sheet of material is in the form of a mesh that is drug eluting and biostable.

Claim 4 (original): The cytostatic anti-proliferative surgical wrap of claim 1 further including at least one additional medication attached to the wrap, the medication being selected from the group that includes an anti-biotic medication, an anti-inflammatory medication or an analgesic medication.

Claim 5 (original): In combination, a cytostatic anti-proliferative drug attached to a surgical suture, the suture being adapted to connect human tissue that is separated by a surgical procedure on a

human subject, the cytostatic anti-proliferative drug being selected from the group that includes sirolimus, anti-sense to c-myc (Resten-NG), tacrolimus (FK506), Everolimus and the following functional analogs of sirolimus: SDZ-RAD, CCI-779, 7-epi- rapamycin, 7-thiomethyl- rapamycin, 7-epi-trimethoxyphenyl- rapamycin, 7-epi-thiomethyl- rapamycin, 7-demethoxy- rapamycin, 32-demethoxy, 2-desmethyl and proline.

Claim 6 (original): In combination, a cytostatic anti-proliferative drug attached to a sheet for placement at an anastomosis of a vessel of the human body, the drug and sheet combination being adapted to prevent narrowing of the vessel at the site of the anastomosis of that vessel, the cytostatic anti-proliferative drug being selected from the group that includes sirolimus, anti-sense to c-myc (Resten-NG), tacrolimus (FK506), Everolimus or any other functional analog of sirolimus including: SDZ-RAD, CCI-779, 7-epi-rapamycin, 7-thiomethyl-rapamycin, 7-epi-trimethoxyphenyl- rapamycin, 7-epi-thiomethyl-rapamycin, 7-demethoxy-rapamycin, 32-demethoxy, 2-desmethyl and proline.

Claim 7 (original): The combination of claim 6 wherein the sheet is in the form of a flat rectangle that is adapted to be placed around a vessel at the site of the anastomosis.

Claim 8 (original): The combination of claim 6 wherein the sheet is in the form of an annulus.

Claim 9 (original): A means for improving the outcome of a surgical procedure on a human subject, the means being the systemic release into the human subject on whom the surgical procedure has been performed of a cytostatic anti-proliferative agent in combination with at least one other drug selected from the group that includes antiseptic agents, anti-biotic agents and

analgesic agents, the cytostatic anti-proliferative agent being selected from the group that includes sirolimus, anti-sense to c-myc (Resten-NG), tacrolimus (FK506), Everolimus and other analog of sirolimus including: SDZ-RAD, CCI-779, 7-epi-rapamycin, 7-thiomethyl-rapamycin, 7-epi-trimethoxyphenyl-rapamycin, 7-epi-thiomethyl-rapamycin, 7-demethoxy- rapamycin, 32-demethoxy, 2-desmethyl and proline.

Claim 10 (original): The means of claim 9 wherein additionally the cytostatic anti-proliferative agent is used in an ointment that is applied to the skin.

Claim 11 (original): The means of claim 9 wherein additionally the cytostatic anti-proliferative agent is attached to a mesh that is adapted to be placed within the human subject in whom the surgical procedure was performed.

Claim 12 (original): The means of claim 9 wherein the cytostatic anti-proliferative agent is attached to a suture.

Claim 13 (original): A method for decreasing the formation of scar tissue after a surgical procedure, the method comprising the following steps:

- a) attaching a cytostatic anti-proliferative drug onto a mesh that is adapted for placement generally around tissue of a human subject; the antiproliferative drug being selected from the group that includes sirolimus, anti-sense to c-myc (Resten-NG), tacrolimus (FK506), Everolimus and any other analog of sirolimus including: SDZ-RAD, CCI-779, 7-epi-rapamycin, 7-thiomethyl-rapamycin, 7-epi-trimethoxyphenyl-rapamycin, 7-

epi-thiomethyl-rapamycin, 7-demethoxy-rapamycin, 32-demethoxy, 2-desmethyl and proline.

- b) placing the mesh with attached cytostatic anti-proliferative drug generally around tissue of the human subject during or after completing a surgical procedure.

Claim 14 (original): The method of claim 13 wherein the surgical procedure includes the forming of an anastomosis of a vessel of the human subject, the vessel being selected from the group that includes an artery, a vein, a ureter, a urethra, an artificial graft, a jejunum, an ileum, a duodenum, a colon, a bile duct or a fallopian tube.

Claim 15 (original): The method of claim 13 further including the step of systemic application into the human subject of at least one cytostatic anti-proliferative drug at least one day prior to the surgical procedure.

Claim 16 (original): The method of claim 13 further including the step of a continuing systemic application into the human subject of at least one cytostatic anti-proliferative drug for at least one day after the surgical procedure.

Claim 17 (original): The method of claim 13 wherein the surgical procedure is the creation of an anastomosis to join a vein to the aorta of the human subject.

Claim 18 (original): The method of claim 13 wherein the surgical procedure is the creation of an anastomosis to join an internal mammary artery to a coronary artery of the human subject.

Claim 19 (original): A method for decreasing scar tissue formation on a cut in the skin of a human subject, the method comprising the following steps:

- a) placing an ointment onto the skin at the site of the cut, the ointment including a cytostatic anti-proliferative agent selected from the group that includes sirolimus, anti-sense to c-myc (Resten-NG), tacrolimus (FK506), Everolimus or any other functional analog of sirolimus including: SDZ-RAD, CCI-779, 7-epi-rapamycin, 7-thiomethyl-rapamycin, 7-epi-trimethoxyphenyl-rapamycin, 7-epi-thiomethyl-, 7-demethoxy- rapamycin, 32-demethoxy, 2-desmethyl and proline; and
- b) placing a bandage over the ointment, the bandage being attached to the skin in the vicinity of the cut.

Claim 20 (original): The method of claim 19 including the step of placing into the ointment at least one additional therapeutic agent that is selected from the group that includes an antiseptic drug, an anti-biotic drug and an analgesic drug.

Claim 21 (original): The method of claim 19 further including the step of the systemic administration of at least one cytostatic anti-proliferative agent selected from the group that includes sirolimus, anti-sense to c-myc (Resten-NG), tacrolimus (FK506), Everolimus and any other functional analog of sirolimus including: SDZ-RAD, CCI-779, 7-epi-rapamycin, 7-thiomethyl-rapamycin, 7-epi-trimethoxyphenyl-rapamycin, 7-epi-thiomethyl-rapamycin, 7-demethoxy- rapamycin, 32-demethoxy, 2-desmethyl and proline.

Claim 22 (currently amended): A sheet for placement at or near the site of a surgical procedure to reduce the formation of scar tissue and adhesions, the sheet including a cytostatic drug that is released from the ~~mesh~~ or sheet over a period that is longer than a day, the cytostatic drug being capable of preventing the initiation of DNA replication of cells in the vicinity of the ~~mesh~~ sheet by acting as a cell cycle mitosis inhibitor that acts on the cells in the vicinity of the ~~mesh~~ sheet at or before the S-phase of cellular mitosis.